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CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail, with sufficient postage, in an envelope addressed to: Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450, on the below date:

Date: August 26, 2005 Name: Magdalena O. Cilella, Ph.D. Signature: *Magdalena Cilella*

BRINKS  
HOFFER  
GILSON  
& LIONE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Appln. of: Steven Goldstein, et al.

Appln. No.: 10/734,096

Filed: December 11, 2003

For: A METHOD OF PRESERVING THE  
TISSUE

Attorney Docket No: 11930/135

Examiner: Barnhart, Lora  
Elizabeth

Art Unit: 1651

Mail Stop Amendment  
Commissioner for Patents  
P. O. Box 1450  
Alexandria, VA 22313-1450

TRANSMITTAL

Sir:

Attached is/are:

- ☒ Third Supplemental Information Disclosure Statement; Form PTO 1449 with required references
- ☒ Return Receipt Postcard

Fee calculation:

- ☒ No additional fee is required.
- ☐ Small Entity.
- ☐ An extension fee in an amount of \$\_\_\_\_\_ for a \_\_\_\_\_-month extension of time under 37 C.F.R. § 1.136(a).
- ☐ A petition or processing fee in an amount of \$\_\_\_\_\_ under 37 C.F.R. § 1.17(\_\_\_\_\_).
- ☐ An additional filing fee has been calculated as shown below:

					Small Entity			Not a Small Entity	
	Claims Remaining After Amendment		Highest No. Previously Paid For	Present Extra	Rate	Add'l Fee	or	Rate	Add'l Fee
Total		Minus			x \$25=			x \$50=	
Indep.		Minus			x 100=			x \$200=	
First Presentation of Multiple Dep. Claim					+\$180=			+\$360=	
					Total	\$		Total	\$

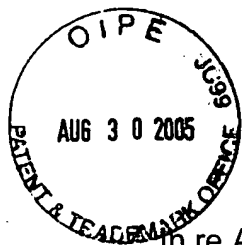
Fee payment:

- ☐ A check in the amount of \$\_\_\_\_\_ is enclosed.
- ☐ Please charge Deposit Account No. 23-1925 in the amount of \$\_\_\_\_\_. A copy of this Transmittal is enclosed for this purpose.
- ☐ Payment by credit card in the amount of \$\_\_\_\_\_ (Form PTO-2038 is attached).
- ☒ The Director is hereby authorized to charge payment of any additional filing fees required under 37 CFR § 1.16 and any patent application processing fees under 37 CFR § 1.17 associated with this paper (including any extension fee required to ensure that this paper is timely filed), or to credit any overpayment, to Deposit Account No. 23-1925.

*August 26, 2005*  
Date

Respectfully submitted,

*Magdalena Cilella*  
Magdalena O. Cilella, Ph.D. (Reg. No. 56,619)



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THIRD SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

In accordance with the duty of disclosure under 37 C.F.R. §1.56 and §§1.97-1.98, and more particularly in accordance with 37 C.F.R. §1.97(c), Applicant hereby cites the following reference(s):

OTHER ART

Butler, D.L., et al., "Gamma Irradiation Effects on Allograft Mechanics", Symposium Biomechanics of Joints and Ligaments, Thursday July 14, 1994 Second World Congress of Biomechanics, Volume II, p. 89

Buxton, George V. et al., "Critical Review of Rate Constants for Reactions of Hydrated Electrons, Hydrogen Atoms and Hydroxyl Radicals (Oh/O) in Aqueous Solution", American Chemical Society and the American Institute of Physics for the National Bureau of Standards, p. 513-886 (1988)

Fuchs, James C.A. et al., "Homograft Aortic Valves Supported by Nonthrombogenic Prosthetic Frames", Proceedings of the 23<sup>rd</sup> Annual Sessions of the Forum on Fundamental Surgical Problems, 53<sup>rd</sup> Clinical Congress of the American College of Surgeons, Chicago, IL, October, 1967, p. 118-119

King, Michael H. et al., "Importance of Technique in Sterilizing and Preserving Human Aortic Valves", Proceedings of the 23<sup>rd</sup> Annual Sessions of the Forum on Fundamental Surgical Problems, 53<sup>rd</sup> Clinical Congress of the American College of Surgeons, Chicago, IL, October, 1967, p. 119-121

Marks, P.H. et al., "Reconstruction of the Cruciate Ligaments with Allografts, Techniques, Results and Perspectives", Orthopaedics (1993) 22:386-391

Schwartz, H.E. et al., "Initial and Long Term Effects of Gamma Irradiation on Goat ACL Allograft Viscoelasticity", ASME, 1995, BED-Vol. 29, 1995 Bioengineering Conference, pp. 205-206

Wardman, Peter, "Reduction Potentials of One-Electron Couples Involving Free Radicals in Aqueous Solution", American Chemical Society and the American Institute of Physics for the National Institute of Standards and Technology, p. 1637-1755 (1989)

Wright, K.A. et al., "Co-operative Studies in the Use of Ionizing Radiation for Sterilization and Preservation of Biological Tissues: Twenty Years' Experience", IAEA-PL-333/12, (1970):107-18

"Virus Inactivation in Plasma Products", Current Studies in Hematology and Blood Transfusion, (1989) 56:1-158

The above references were previously submitted to the Examiner with the Information Disclosure Statements filed on January 27, 2005 and March 2, 2005. However, the Examiner noted that the dates of the publication were not included with the listed references. Applicant now provides the appropriate dates of publication. Applicant notes that these citations are identical to those previously submitted in the two Information Disclosure Statements. Because the listed references were submitted prior to the issuance of the first Office action, Applicant believes that no additional fee is required in connection with this Third Supplemental Information Disclosure Statement.

Applicant is enclosing Form PTO-1449 (one sheet) along with a copy of each listed reference for which a copy is required under 37 C.F.R. §1.98(a)(2). As the listed references are in English, no further commentary is believed to be necessary, 37 C.F.R. §1.98(a)(3). Applicant respectfully requests the Examiner's consideration of the above references and entry thereof into the record of this application.

By submitting this Statement, Applicant is attempting to fully comply with the duty of candor and good faith mandated by 37 C.F.R. §1.56. As such, this Statement is not intended to constitute an admission that any of the enclosed references, or other information referred to therein, constitutes "prior art" or is otherwise "material to patentability," as that phrase is defined in 37 C.F.R. §1.56(a).

Respectfully submitted,

August 26, 2005  
Date

Magdalena O. Cilella  
Magdalena O. Cilella, Ph.D.  
(Reg. No. 56,619)



FORM PTO-1449	SERIAL NO. 10/734,096	CASE NO. 11930/135
LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT	FILING DATE December 11, 2003	GROUP ART UNIT 1651
(use several sheets if necessary)		APPLICANT(S): Goldstein, Steven et al.

## REFERENCE DESIGNATION

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER <small>Number-Kind Code (if known)</small>	DATE	NAME	CLASS/ SUBCLASS	FILING DATE

## FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER <small>Number-Kind Code (if known)</small>	DATE	COUNTRY	CLASS/ SUBCLASS	TRANSLATION YES OR NO

EXAMINER INITIAL	OTHER ART – NON PATENT LITERATURE DOCUMENTS <small>(Include name of author, title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date page(s), volume-issue number(s), publisher, city and/or country where published.</small>	
	C1	Butler, D.L., et al., "Gamma Irradiation Effects on Allograt Mechanics", Symposium Biomechanics of Joints and Ligaments, Thursday July 14, 1994 Second World Congress of Biomechanics, Volume II, p. 89
	C2	Buxton, George V. et al., "Critical Review of Rate Constants for Reactions of Hydrated Electrons, Hydrogen Atoms and Hydroxyl Radicals (Oh/O) in Aqueous Solution", American Chemical Society and the American Institute of Physics for the National Bureau of Standards, p. 513-886 (1988)
	C3	Fuchs, James C.A. et al., "Homograft Aortic Valves Supported by Nonthrombogenic Prosthetic Frames", Proceedings of the 23 <sup>rd</sup> Annual Sessions of the Forum on Fundamental Surgical Problems, 53 <sup>rd</sup> Clinical Congress of the American College of Surgeons, Chicago, IL, October, 1967, p. 118-119
	C4	King, Michael H. et al., "Importance of Technique in Sterilizing and Preserving Humanortic Valves", Proceedings of the 23 <sup>rd</sup> Annual Sessions of the Forum on Fundamental Surgical Problems, 53 <sup>rd</sup> Clinical Congress of the American College of Surgeons, Chicago, IL, October, 1967, p. 119-121
	C5	Marks, P.H. et al., "Reconstruction of the Cruciate Ligaments with Allografts, Techniques, Results and Perspectives", Orthopade (1993) 22:386-391
	C6	Schwartz, H.E. et al., "Initial and Long Term Effects of Gamma Irradiation on Goat ACL Allograft Viscoelasticity", ASME, 1995, BED-Vol. 29, 1995 Bioengineering Conference, pp. 205-206
	C7	Wardman, Peter, "Reduction Potentials of One-Electron Couples Involving Free Radicals in Aqueous Solution", American Chemical Society and the American Institute of Physics for the National Institute of Standards and Technology, p. 1637-1755 (1989)
	C8	Wright, K.A. et al., "Co-operative Studies in the Use of Ionizing Radiation for Sterilization and Preservation of Biological Tissues: Twenty Years' Experience", IAEA-PL-333/12, (1970):107-18
	C9	"Virus Inactivation in Plasma Products", Current Studies in Hematology and Blood Transfusion, (1989) 56:1-158

EXAMINER	DATE CONSIDERED
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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.